

SUPPORT FOR THE AMENDMENTS

Applicants have rewritten Claim 1 as new Claim 8 to incorporate the limitations of Claim 3. Accordingly, support for new Claim 8 can be found in Claims 1 and 3, as previously presented. Claims 2 and 4-7 have been rewritten as new Claims 9-13. Thus, support for new Claims 9-13 can be found in Claims 2 and 4-7, as previously presented.

No new matter has been added. Claims 8-13 are active in this application.

REMARKS/ARGUMENTS

Present Claims 8-11 relate to 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride having a melting range of 180-200°C determined by differential scanning calorimetry and a X-ray powder diffraction pattern having one or more of the following characteristic peaks: 12.2; 13.6; 16.3; 18.0; 18.2; 19.2; 21.4; 21.9; 22.8; 23.5; 24.2; 24.9; 26.6; 28.5; 29.4; 29.9; and 33.9±0.2 degrees/2θ and

a degree of crystallinity, expressed as weight % based on the total weight of said 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride, of at least 90 weight %.

Present Claims 12 and 13 relate to processes for preparing such 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride.

Thus, all of the present claims require the presence of 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride (TA 2005) which has a degree of crystallinity of at least 90 weight %. The cited references neither disclose nor suggest TA 2005 which has such a degree of

crystallinity. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claims 1-7 under 35 U.S.C. § 102(b) in view of U.S. Patent Nos. 6,287,540 (Trofast '540) and 6,030,604 (Trofast '604) and the rejection of Claims 1-7 under 35 U.S.C. § 103(a) in view of Trofast '540 and Trofast '604 are respectfully traversed. On page _ of the Office Action, it is asserted that Trofast '540 and Trofast '604 disclose TA 2005 and methods of making TA 2005. This assertion is, however, incorrect. In fact, these references only mention TA 2005 in passing in a laundry list of active agents which can be used

A potent pharmaceutically active substance suitable for use in the invention is, for example, an antiarrhythmic drug, tranquilizer, cardiac glycoside, hormone, hypertensive drug, antidiabetic or anticancer drug, sedative or analgesic drug, antibiotic, antirheumatic drug, immunotherapy, antifungal or antihypotension drug, vaccine, antiviral drug, protein (e.g. insulin), peptide, vitamin, or a cell surface receptor blocker. It is preferably a glucocorticosteroid, particularly one which is metabolized rapidly, for example beclomethasone dipropionate (BDP), beclomethasone monopropionate (BMP), flunisolide, triamcinolone acetonide, fluticasone propionate, ciclesonide, budesonide, rofleponide or derivatives thereof, mometasone, tipredane, RPR 106541 and/or a β 2-agonist such as terbutaline, salbutamol, formoterol, salmeterol, TA 2005, pircumarol or a pharmaceutically acceptable salt thereof; and/or a prophylactic agent such as sodium chromoglycate or nedocromil sodium.

Trofast '540, col. 1, lines 38-54; Trofast '604, col. 1, lines 38-54.

Thus, there is nothing in either of these references about the synthesis of TA 2005. Moreover, there is nothing in either of these references which would suggest the ability to obtain TA 2005 having the presently claimed melting point range, PXRD peak(s), and degree of crystallinity.

In contrast, when the prior art as a whole is considered, it is clear that the presently claimed TA 2005 is novel and unobvious. In this regard, the Examiner's attention is directed toward U.S. Patent No. 4,579,854 (Iwakuma et al.), a copy of which was submitted with the Information Disclosure Statement filed on September 20, 2006. Iwakuma et al. corresponds

to European patent, EP 0 147 719, which is cited on page 2, of the present application. As explained in the specification, TA 2005 is prepared in Example 4, step (3-a) and is reported to have a melting point of 170.0-171.5°C (decomp.). In sharp contrast, the TA 2005 of the present claims has a melting point of 180-200°C. Clearly, the presently claimed TA 2005 is of a different form than that prepared in Iwakuma et al.

Further, there is nothing in either Trofast '540 nor Trofast '604 which would lead one of skill in the art that the TA 2005 referred to in these references was not the same as that disclosed in Iwakuma et al.

For all of these reasons, the rejection is improper and should be withdrawn.

Although the present claims are not rejected in view of U.S. Patent Publication Nos. 2009/0280068 (Pivetti et al. '068) and 2009/0326231 (Pivetti et al. '231), on page 4 of the Office Action, it is asserted that the present claims conflict with those of the cited publications. This assertion is, however, incorrect. Specifically, the present claims are require a specific melting point and degree of crystallinity. In contrast, the claims of Pivetti et al. '068 do not recite these limitations. Moreover, the claims of Pivetti et al. '068 all require the presence of a PXRD peak at 3.39, which is absent from the present claims. Lastly, the claimed methods recite the use of different solvents. Similarly, the claims of Pivetti et al. '068 do not recite the presently claimed melting point, PXRD peak(s), or degree of crystallinity. Thus, the present claims are clearly not in conflict with those of Pivetti et al. '068 or Pivetti et al. '231.


The rejection of Claims 3-5 under 35 U.S.C. § 112, second paragraph, has been obviated by amendment. As the Examiner will note, the claims have been rewritten such that they are free of the criticism outlined on page 2 of the Office Action. Accordingly, the rejection should be withdrawn.

Lastly, Applicants are filing herewith a Supplemental Application Data Sheet to correct a typographical error in the title. Support for the corrected title can be found on page 1 of the specification, as originally filed.

Applicants submit that the present application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Stephen G. Baxter', is written over a horizontal line.

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